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April 19, 2007

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
**Attn: Kimberly Terrell**  
**Manager, Publication and Issuance Branch**

Re: Request for Expedited Issuance  
U.S. Patent Application Serial No. 10/627,372  
Title: NOVEL PPAR LIGANDS THAT DO NOT CAUSE FLUID  
RETENTION, EDEMA OR CONGESTIVE HEART FAILURE  
Inventor: Harrihar A. PERSHADSINGH  
Filed on: July 24, 2003  
Attorney Docket No.: 42184-20004.00  
Confirmation No.: 2447  
Art Unit: 1614  
Examiner: B. Kwon

Dear Sir or Madam:

Applicant requests your assistance in expediting the issuance of their Application No. 10/627,372. The Notice of Allowance for this application was mailed on April 10, 2007 and the Issue Fee was transmitted via facsimile on April 13, 2007, along with a notification of change in entity status. Copies of the Notice of Allowance and Issue Fee Transmittal are enclosed herewith.

Applicant's request for expedited issuance is necessitated by the imminent marketing approval of products covered by the allowed claims in the above-referenced patent application being obtained by a licensee of the patent. In spite of Applicant's best efforts, prosecution and processing of the application has been unduly delayed at the Group Art Unit and the Examining division. Any additional time required in obtaining issuance of patent may cause serious economic damage to Applicant and may hinder the efforts of the licensee in bringing the products to market.

Unnecessary and avoidable delays in prosecuting the application are described in brief as follows: The application was filed on July 24, 2003. The first Office Action was mailed by Examiner K. Weddington on January 26, 2005. Applicant responded to the Office Action with amendments on April 6, 2005. A Final Rejection was mailed on June 29,

pa-1147234

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2005. Following consultation with the Examiner, Applicant amended the claims to correspond to subject matter considered allowable by the Examiner within the two month expedited period on August 26, 2005. By this time Applicants had alerted the Examiner about the need for expediting the prosecution of the application and also the willingness of the Applicant to work with the Examiner in presenting claims that could be found allowable by the Examiner. An Advisory Action mailed October 24, 2005 indicated that only a single issue of obviousness-type double patenting remained to be addressed. Applicant promptly filed a terminal disclaimer to address the issue.

Instead of the expected allowance, Applicant received a non-Final rejection on January 3, 2006 over a newly cited reference. Applicant filed a response on January 31, 2006. Applicant also placed several calls to the Examiner emphasizing the urgency of obtaining issuance and reiterating Applicant's willingness to further amend claims if necessary to expedite prosecution. A Final rejection was mailed on May 5, 2006. Applicant discussed the rejections put forth by the Examiner and filed further amendments on June 30, 2006, to remove claim language objected to by the Examiner and also incorporate all suggestions for amendments made by the Examiner, with the expectation that no further issues remained for a determination of allowability by the PTO. Applicant made several attempts to follow up with the Examiner but was unable to contact the Examiner.

On September 26, 2006 Applicant received an Advisory Action from a different Examiner, N. Zhang. The Advisory Action indicated that the amendments suggested by Examiner Weddington to overcome the single cited reference were not sufficient. Applicant held a telephonic interview with Examiner Zhang and Supervisor A. Marschel on November 7, 2006. Applicant agreed to amend the claims to distinguish the cited reference, however Examiner Zhang and her supervisor objected to claim terms that had been introduced on the suggestion of the previous examiner, Mr. Weddington. Based on the suggestions of Examiner Zhang and Supervisor Marschel, Applicant submitted additional amendments on November 30, 2006, with the expectation that these were sufficient to overcome any remaining objections. Applicant subsequently contacted Examiner Zhang several times to determine the status of the application, reiterate the increasing urgency for obtaining allowance and again reiterate the willingness to make any additional amendments that may be necessary to obtain prompt allowance.

In early February, 2007, Applicant was informed that Examiner Zhang would no longer be responsible for the Application and the case had been assigned to Examiner B. Kwon, the *third* examiner. Applicant held several discussions with Examiner Kwon and telephonically agreed to Examiner's amendments to put the application in condition for allowance. Examiner Kwon prepared a Notice of Allowance by March 12, 2007.

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Further, due to the repeated delays, all extension periods were exhausted prior to allowance and Applicant was compelled to file a Request for Continued Examination on March 7, 2007 in order to keep the application pending. Unfortunately, the Patent Office mistakenly determined that the application was under a non-Final rejection, and due to this PTO error deemed the RCE filing improper. The PTO did not notify Applicant of this problem, rather Applicant discovered it by constantly checking the public PAIR transaction history. As soon as Applicant was aware of the issue, Applicant's representative immediately contacted the office on April 2, 4, and 5, 2007 to resolve the error. The Notice of Allowance was finally mailed on April 10, 2006 -- over one month after the Examiner had completed the Notice of Allowance form.

Applicant repeatedly tried to impress upon each examiner the urgency for a prompt examination and allowance, and diligently accepted all suggestions for amendments made by each examiner. Applicant did not avail of any extensions throughout the prosecution except those necessary to allow the Patent Office time for further prosecution.

As described above, examination was unduly delayed by replacement of the responsible examiner twice, with each examiner disagreeing with determinations of patentability made by the previous examiner and requiring further amendments and prosecution.

In addition, processing errors at the PTO further compounded the delay in sending the Notice of Allowance. Now, Applicant and his licensee are in jeopardy of receiving marketing approval for their product while delay in issuance of the relevant patent results in economic damage and delays in entering the market.

Therefore, Applicant respectfully requests your assistance in expediting the issuance of the aforementioned application, and help in alleviating the situation and minimizing any harm to the Applicant that may result from these unfortunate delays.

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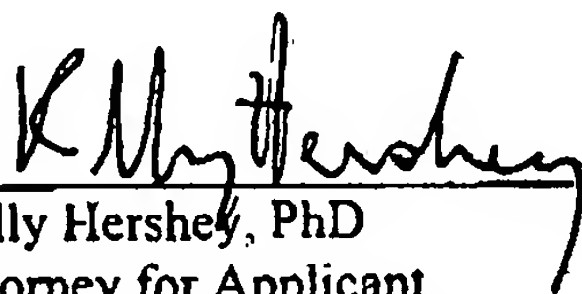
April 19, 2007

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In the event the U.S. Patent and Trademark Office determines that a fee or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with expediting issuance of this patent to Deposit Account No. 03-1952 referencing docket no. 421842000400.

We very much appreciate your assistance with this urgent matter.

Respectfully submitted,



Kelly Hershey, PhD

Attorney for Applicant

Registration No.: 48,408

MORRISON & FOERSTER LLP

755 Page Mill Road

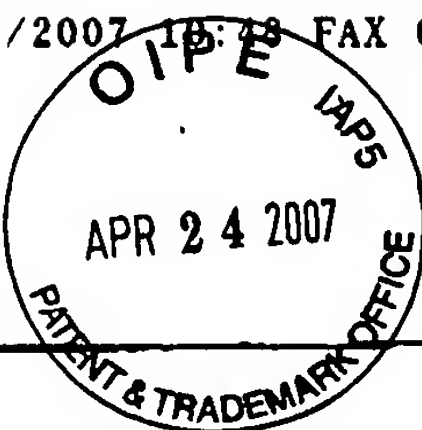
Palo Alto, California 94304-1018

(650) 813-5755

Enclosures:

Notice of Allowance

Issue Fee Payment

**Notice of Allowability**

Application No.

10/627,372

Examiner

Brian S. Kwon

Applicant(s)

PERSHADSINGH, HARRIHAR A.

Art Unit

1614

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 2/15/07 and Telephonic Interview on 3/23/07.
2. ☒ The allowed claim(s) is/are 1-3, 9, 10, 12 and 14-15.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 20070312.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

BRIAN-YONG S. KWON  
PRIMARY EXAMINER

Application/Control Number: 10/627,372  
Art Unit: 1614

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***Request for Continued Examination (RCE)***

1. Acknowledgement is made of applicants' filing of the instant application on March 07, 2007 as a Request for Continued Examination (RCE) under 37 CFR 1.1114.

**EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shantanu Basu on 03/23/07.

The application has been amended as follows:

In Claim 1, lines 2-4, delete [, or treating an inflammatory or metabolic disorder selected from the group consisting of metabolic syndrome, and inflammation caused by osteoarthritis].

In Claim 1, line 5, delete [, or an analog thereof].

In Claim 1, lines 5-7, delete [(a) at least partially activate peroxisome proliferation activated receptors (PPARs) and (b) at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors] and replace with --increase the activity of a peroxisome proliferators activated receptor (PPAR) gamma--.

In Claim 2, lines 3-4, delete [, or treating the inflammatory or metabolic disorder].

In Claims 3, 9 and 10, lines 1-2, delete [, or an analog thereof].



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Art Unit: 1614

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In Claim 12, line 1, delete [the] before "total" and replace with --a--.

Claims 4-7 are cancelled.

**Conclusion**

3. Claims 1, 2, 3, 9, 10, 12 and 14-15 are allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon  
**Primary Patent Examiner**  
**AU 1614**





# Interview Summary

Application No.

10/827,372

Applicant(s)

PERSHADSINGH, HARRIHAR A.

Examiner

Brian S. Kwon

Art Unit

1614

All participants (applicant, applicant's representative, PTO personnel):

(1) Brian S. Kwon

(3) \_\_\_\_\_

(2) Shantanu Basu

(4) \_\_\_\_\_

Date of Interview: 23 March 2007

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal (copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: 1-7, 9, 10 and 12

Identification of prior art discussed: n/a

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Authorization was given to amend claims 1-7, 9, 10 and 12 by Examiner's Amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
Examiner's signature, if required



## Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

**Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**

**Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

**37 CFR §1.2 Business to be transacted in writing.**

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Serial Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.